510 (k) Summary for: **K 120004**

Summary of Safety and Effectiveness for Digital Thermometer

This summary of 510 (k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's Identification:

AUG 2 3 2012

CHINA (Shenyang) Med-land Imp/Exp Corp., Ltd
NO. 255 New Jinqiao Road, Room 513
Pudong, Shanghai, P.R. of China, 201206 CHINA

Contact person: Ann D. McGonigle, MPH
A.D. McGonigle Consulting
Wayland, MA 01778

Contact Telephone Number: (508) 358-9114

Date Prepared: August 20, 2012

2. Name of the Device:

Digital Thermometer

2.1 Model Nos.:

YT301 / YT302 / YT303

2.2 Regulatory information:

A. Regulation section: 880.2910, Clinical Electronic Thermometer
B. Classification: Class II
C. Product Code: FLL
D. Panel: 80 General Hospital

3. Predicate Device Information:

MicroLife Digital Thermometer

4. Device Description:

The Digital Thermometer is a hand-held electronic thermometer comprised of an electronic thermoresistor (thermistor) sensor connected to a printed circuit board (PCB) with liquid crystal display (LCD) user readout. These components are held in a plastic housing with stainless steel metal cap. The housing is a rigid plastic. The Digital Thermometer is supplied with a clear plastic storage case to protect the thermometer.

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5. Intended Use:

The Digital Thermometer is used for the measurement and monitoring of human body temperature. Body temperature can be measured with the Digital Thermometer by oral, axillary (under the arm) and rectal methods. The device is for adult and pediatric use.

6. Comparison to Predicate Device:

The Digital Thermometer is substantially equivalent to the predicate device.

Indication:	Identical to the predicate device
Technology:	Similar means of measuring temperature to the predicate device.
Materials:	Materials have been testing in accordance with ISO 10993 and compare to the results of the predicate device.
Environment for Use:	Identical to predicate device.
Patient Population:	Identical to predicate device.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

The Digital Thermometer has demonstrated compliance to applicable Voluntary standards of performance and safety, including voluntary standards for Clinical Electronic Thermometers, Medical Electrical Safety, and Biological Evaluation of Medical Devices (ASTM E1112-00, IEC 60601-1, IEC 60601-1-2 and ISO 10993-1).

8. Conclusions

The Digital Thermometer has the same intended use and similar technological characteristics as the approved predicate device, MicroLife Digital Thermometer. Verification and validation tests contained in the submission demonstrate that any differences in characteristics do not raise any new questions of safety or effectiveness. If there are any engineering differences, these do not affect the intended use or alter the fundamental scientific technology of the approved predicate device, MicroLife Digital Thermometer.

Therefore, the Digital Thermometer is substantially equivalent to the predicate device, MicroLife Digital Thermometer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

China Shenyang Med-Land Imp/Exp Corporation, Limited
C/O Ms. Ann D. McGonigle
Regulatory Consultant
A.D. McGonigle Consulting
19 Sedgemeadow Road
Wayland, Massachusetts 01778

AUG 2 3 2012

Re: K120004
Trade/Device Name: Digital Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 17, 2012
Received: July 24, 2012

Dear Ms. McGonigle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

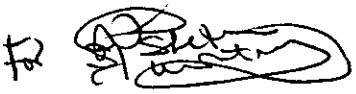
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Indications for Use of the Device

510 (k) No.: K 120004

Device Name: Digital Thermometer

Indications for Use:

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Prescription Use _____ AND/OR Over the counter Use ___X_____
(Part 21CFR 801 Subpart D) (Part 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C Chapman 8/22/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120004